

## REMARKS

The Non-final Office Action mailed April 23, 2008, has been received and reviewed. Each of claims 1–27 stands rejected. Claim 10 has been amended herein and claim 13 has been canceled. Accordingly, claims 1–12 and 14–27 remain pending. Care has been exercised to introduce no new subject matter. Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested.

### **Rejections based on 35 U.S.C. § 102**

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also*, MPEP § 2131.

Claims 1–27 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Publication Number 2002/0188469 to Shalmi et al. (hereinafter the “Shalmi reference”). As the Shalmi reference fails to describe, either expressly or inherently, each and every element of claims 1–12 and 14–27, Applicants respectfully traverse the rejection, as hereinafter set forth.

Independent claim 1 recites a system for managing clinically related supply procurement according to outcomes. The system includes a first interface to receive patient supply data captured from at least one clinically related site, the patient supply data comprising clinical supplies used to treat one or more patients. The system also includes a second interface to receive clinical outcomes data that describes one or more patient outcomes that resulted from

using the clinical supplies from the at least one clinically related site. The system further includes an analytic engine. The analytic engine communicates with the first interface and the second interface to generate comparative clinical supply reports based at least on the clinical outcomes data.

The Shalmi reference, on the other hand, describes a pharmaceutical distribution and sales system by which a drug manufacturer contracts with a customer (e.g. a hospital) to supply certain quantities of the drug based on potential patient use. The purpose of the system is to minimize financial risk for customers purchasing the costly drugs, while at the same time ensuring an adequate supply of drugs for patients. *See* Shalmi reference Abstract. The Shalmi reference describes tracking customer inventory to make sure adequate supplies of drugs are available. *See* Shalmi reference [0053].

Applicants respectfully assert that the Shalmi reference fails to describe, either expressly or inherently, an “interface to receive clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies.” Thus, the clinical outcomes data describes the outcome or result of the patient’s treatment based on data obtained after the treatment with clinical supplies. In contrast, the Shalmi reference describes tracking a customer’s use of a drug provided by a manufacturer. The Shalmi reference describes receiving a customer order when the supply of a drug falls below a limit, or directly tracking a customer’s drug inventory. *Id.* The drug inventory information is not patient specific and does not describe the outcome or result of treatment with a drug. Thus, the Shalmi reference does not describe an “interface to receive clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies.”

Further, Applicants respectfully assert that the Shalmi reference does not describe an “analytic engine communicating with the first interface and the second interface to generate comparative clinical supply reports based at least on the clinical outcomes data.” The analytic engine in claim 1 compares patient usage data for a clinical supply with the aggregated outcomes experienced by the patient as a result of using the supply. In contrast, the Shalmi reference describes analyzing historical usage data to anticipate future usage data. The anticipated usage data forms the basis of a supply agreement between a customer and manufacturer. *Id.* at [0056]. The analysis in the Shalmi reference does not consider the result or outcome experienced by the patient nor correlate the outcome with supply data. Thus, an “interface to receive clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies” is not described by the Shalmi reference.

As the Shalmi reference fails to describe, either expressly or inherently, every element of independent claim 1, Applicants respectfully submit that claim 1 is not anticipated by the Shalmi reference. Each of claims 2-9 depends, either directly or indirectly, from independent claim 1 and define further patentable features. For example, claim 4 recites a system according to claim 1, wherein the clinical outcomes data comprises at least one of patient mortality data, patient morbidity data, patient ambulatory data, patient infection data, patient prescription data, patient length of stay data, patient condition data, and patient readmittance data. It is stated in the Office Action of January 23, 2008, that “patient prescription data” is described in paragraph [0053] of the Shalmi reference. *See* Office Action p. 3. Applicants submit that “patient prescription data” is not described in the cited section, or any other part, of the Shalmi reference. To the contrary, this section of the Shalmi reference describes tracking the amount of a hemostatic agent used to treat patients. *See* Shalmi reference [0053]. This is unrelated to patient

prescription data that provides information about a patient outcome. Accordingly, the Shalmi reference does not anticipate claim 4.

Accordingly, it is respectfully submitted that claims 2-9 are not anticipated by the Shalmi reference for at least the above-cited reasons. As such, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 1-9 is respectfully requested.

As presently amended, independent claim 10 recites a method for managing clinically related supply procurement according to outcomes. The method includes receiving patient supply data captured from at least one clinically related site. The patient supply data comprises clinical supplies used to treat one or more patients. The method also includes receiving clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies from the at least one clinically related site, wherein the outcome data is patient condition data. The method further includes generating comparative clinical supply reports based at least on the clinical outcomes data.

For reasons similar to those given with reference to claim 1, Applicants respectfully assert that the Shalmi reference does not describe “receiving clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies from the at least one clinically related site” and “generating comparative clinical supply reports based at least on the clinical outcomes data” as recited in claim 10. Further, claim 10 has been amended to describe an embodiment where the outcomes data is “patient condition data.” In other words, the outcome that results from using the clinical supply is described in terms of a patient condition. In contrast, the Shalmi reference describes tracking drug usage on the inventory level, but not with reference to specific patients. *Id.* The Shalmi describes various maladies suffered by patients. *Id.* at [0004]. But, the Shalmi reference does not describe

receiving information about a patient's condition after the patient is treated with a clinical supply. Accordingly, the Shalmi reference does not describe "receiving clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies from the at least one clinically related site, wherein the outcome data is patient condition data."

As the Shalmi reference fails to describe, either expressly or inherently, each and every element recited in claim 10, it is respectfully submitted that the Shalmi reference does not anticipate independent claim 10. Each of claims 11-12 and 14-18 depends, either directly or indirectly, from independent claim 10. Accordingly, each of these claims is not anticipated by the Shalmi reference for at least the above-cited reasons. As such, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 10-12 and 14-18 is respectfully requested.

Independent claim 19, as amended herein, recites one or more computer-readable media having computer-executable instructions embodied thereon for performing a method for managing clinically related supply procurement according to outcomes. The method includes receiving patient supply data captured from at least one clinically related site. The patient supply data comprises clinical supplies used to treat one or more patients. The method also includes receiving clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies from the at least one clinically related site. The method further includes generating a comparative clinical supply report based at least on the clinical outcomes data and storing the comparative clinical supply report in computer accessible memory.

It is respectfully submitted that the Shalmi reference fails to describe, either expressly or inherently, managing clinically related supply procurement according to outcomes, as recited in independent claim 19. More particularly, the Shalmi reference fails to describe, either expressly or inherently, a computer readable media with computer readable instructions

“to receive clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies” or “generating comparative clinical supply reports based at least on the clinical outcomes data.” As described previously with reference to claim 1, the Shalmi reference does not describe tracking or utilizing clinical outcomes data at all.

As the Shalmi reference fails to describe, either expressly or inherently, each and every element recited in amended independent claim 19, it is respectfully submitted that the Shalmi reference does not anticipate independent claim 19, as amended herein. Each of claims 20-27 depends, either directly or indirectly, from independent claim 19. Accordingly, each of these claims is not anticipated by the Shalmi reference for at least the above-cited reasons. As such, withdrawal of the 35 U.S.C. § 102(b) rejection of claims 19-27 is respectfully requested

**CONCLUSION**

For at least the reasons stated above, claims 1–12 and 14–27 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or johoward@shb.com (such communication via email is herein expressly granted) – to resolve the same.

It is believed that no fee is due in conjunction with the present amendment. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing Attorney Docket No. CRNI.111421.

Respectfully submitted,

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